Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	GC Europe N.V.
Manufacturer address and contact details	Research Park Interleuvenlaan 33 B-3001 Leuven Belgium
Single Registration Number (SRN) (if available)	BE-MF-000001608

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	BSI □ See attached schedule 1 and 2
Notified body number (if applicable)	2797 □ See attached schedule 1 and 2
Directive Certificate number(s) to which this confirmation is made (if applicable)	CE 01488 MED 31385 □ See attached schedule 1
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if	CE 01488 expiry date: 2024-05-06 MED 31385 expiry date: 2024-05-26

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

applicable)	□ See attached schedule 1
End date of extended validity/transition period	2028-12-31 □ See attached schedule 1 and 2

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule 1) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule 1 and 2 and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s)

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule 1 or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Up classified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule 2 or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule 1 and 2**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: GC Europe NV

Location & Date: Leuven, 24 June 2024

Signature, Print Name, Title:



Mario Minale, Head of Regulatory Affairs

Contact Details (at least email): mario.minale@gc.dental

Schedule of Devices 1

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
GC Fuji II LC (Improved) GC Fuji II LC CAPSULE	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji PLUS GC Fuji PLUS CAPSULE GC Fuji PLUST EWT	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji I CAPSULE GC Fuji I	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji BOND LC	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji BULK	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji ORTHO	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji ORTHO LC CAPSULE GC Fuji ORTHO LC	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji LINING LC	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji IX GP CAPSULE GC Fuji IX GP GC Fuji IX GP EXTRA GC Fuji IX GP FAST	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuj II CAPSULE GC Fuj II	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Miracle Mix CAPSULE Miracle Mix	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

DENTIN CONDITIONER	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji PLUS CONDITIONER	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
CAVITY CONDITIONER	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
ORTHO CONDITIONER	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji COAT LC	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC FujiCEM	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji TRIAGE CAPSULE GC Fuji TRIAGE	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji VII CAPSULE	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji ORTHO BAND PASTE PAK	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji LINING LC PASTE PAK	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
G-COAT PLUS	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji VIII GP CAPSULE	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
EQUIA (EQUIA Fil/EQUIA Coat)	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji ORTHO BAND LC PASTE PAK (Automix Compatible)	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji ORTHO LC PASTE PAK Automix	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
ORTHO GEL CONDITIONER	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji TEMP LT	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC FujiCEM 2	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
EQUIA Forte(EQUIA Forte Fil/EQUIA Forte Coat)	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC FujiCEM Evolve	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
EQUIA Forte HT(EQUIA Forte HT Fil /EQUIA Forte Coat)	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
FREEGENOL TEMPORARY PACK	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
TEMPRON	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
REBARON	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
UNIFAST Trad	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
UNIFAST III	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
PATTERN RESIN LS	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A

UNIFAST LC	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
CAVITON	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GRADIA	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GRADIA gum shades	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
REVOTEK LC	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GRADIA DIRECT	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GRADIA DIRECT X	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GRADIA DIRECT Flo GRADIA DIRECT LoFlo	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
G-BOND G-BOND Unit Dose	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
G-CEM CAPSULE	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
OPTIGLAZE	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GRADIA CORE	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC KALORE	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
G-ænial	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
G-ænial Universal Flo	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
G-ænial Bond	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
everStickC&B	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
everStickORTHO	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
everStickPERIO	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
everStickPOST	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
everStickNET	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
everStickPOST INTRO	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Stick	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
StickNET	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
everX Posterior	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
everStickINTRO	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
CERASMART	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
OPTIGLAZE color	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
G-ÆNIAL FLO X	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
CERAMIC PRIMER II	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Initial CAST NP	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC KommonBase	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Ortho Connect	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC ETCHANT	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Ortho Etching Gel	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GRADIA PLUS	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A

G-Premio BOND	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Essentia	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Ortho Connect Flow	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
METAL PRIMER Z	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Acrylic Primer	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
G-CEM LinkForce	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
G-Multi PRIMER	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC RELINE II	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Initial LiSi Press	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Initial LiSi Block	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
G-ænial Universal Injectable	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Modeling Liquid	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
G-CEM Veneer	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
G-ænial A'CHORD	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
everX Flow	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
CERASMART 270	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Aligner Connect	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC RELINE	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Solare Universal Bond	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Essentia HiFlo	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
SOLARE Flo	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
SOLARE X	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Essentia LoFlo	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Composite Primer	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Tempsmart DC	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
G-CEM ONE	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
G2-BOND UNIVERSAL	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Creation VC Make up Neo	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Creation VC Composite Primer	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Creation VC FLOW Dentin	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Creation VC Ceramic Primer	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Creation VC Metal Primer	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Creation VC Veneering Composite	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Creation VC Gingiva	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Creation LS Press	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Initial	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A

Kooliner	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
COE-PAK COE-PAK AUTOMIX NDS	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
COE-COMFORT	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
COE-SOFT	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC Fuji VII EP CAPSULE	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
Fiber Post	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
PATTERN RESIN	CE 01488	2024-05-06	BSI 2797	BSI 2797	2028-12-31	N/A
GC TEMP PRINT	MED 31385	2024-05-26	KIWA 0476	BSI 2797	2028-12-31	N/A
MI Varnish	MED 31385	2024-05-26	KIWA 0476	BSI 2797	2028-12-31	N/A
Bite Force Analyzer (Dental Prescale II)	MED 31385	2024-05-26	KIWA 0476	BSI 2797	2028-12-31	N/A

Schedule of Devices 2

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[4] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
SOFT-LINER	N/A	N/A	N/A	BSI 2797	2028-12-31	N/A
Dry Mouth Gel	N/A	N/A	N/A	BSI 2797	2028-12-31	N/A
GC MI Paste Plus	N/A	N/A	N/A	BSI 2797	2028-12-31	N/A
GC Tooth Mousse Plus	N/A	N/A	N/A	BSI 2797	2028-12-31	N/A
GC Tooth Mousse	N/A	N/A	N/A	BSI 2797	2028-12-31	N/A
GC Fiber Post Dril	N/A	N/A	N/A	BSI 2797	2028-12-31	N/A
DIAPOLISHER PASTE	N/A	N/A	N/A	BSI 2797	2028-12-31	N/A

[4] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)